REMARKS

Status of the claims

Claims 11-13 are pending in this application. Claim 1 has been amended to recite a method of treating an acute or chronic rejection reaction of a xenograft transplant recipient to a xenograft transplant, which comprises administering to the recipient receiving the xenograft a therapeutically effective amount of a certain leflunomide product. Support for the amendment to the claim appears in the specification at page 3, lines 6-12.

Information Disclosure Statement

Applicants filed an Information Disclosure Statement with this continuation application on July 25, 2003. Applicants respectfully request that the Examiner return the initialed PTO 1449 form in the next communication from the Office.

Obviousness-type double patenting rejection

Claims 11-13 were rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-10, 1-13 and 1-5 of U.S. Patent Nos. 4,965,276, 5,728,721 and 6,133,301, respectively. In support of the rejection, the Examiner stated that the claims of the '276 and '301 patents, and claims 1-7 of the '721 patent, "encompass the instant claims regarding xenografts." The Examiner also stated that claims 8-13 of the '721 patent "encompass the instant claims regarding the acute and chronic rejections of the xenografts."

Applicants enclose a Terminal Disclaimer to overcome the rejection as it relates to the '301 patent. The filing of this Terminal Disclaimer to obviate the rejection does not constitute an admission of the propriety of the rejection. *See* MPEP § 804.02.

Applicants traverse the double patenting rejection made in view of U.S. Patent No. 4,965,276. Claims 1-10 of the '276 patent recite methods of treating chronic graft-versus-host diseases. In other words, the methods of the '276 patent counter rejections originating from the transplant and directed against the patient. In contrast, the methods of the present invention counter rejections originating from the patient and directed against the transplant. The present invention distinguishes these different

rejection reactions at page 2, lines 9-11 (citing EP A 217, 206, a counterpart of the '276 patent, as treating graft-versus-host rejections) and at page 3, lines 6-12 (citing the present invention as relating to the treatment of graft rejection reactions of the patient to the transplant). For at least this reason, the claims of the '276 patent do not "encompass the instant claims regarding xenografts" as suggested in the Office Action and do not render the present claims obvious.

In addition, the '276 patent does not disclose using the recited compounds in treating rejection reactions involving an organ from a different species. Rather, the '276 patent discloses only transplants involving animals of the same species. *See* col. 2, line 50 to col. 3, line 3. For this additional reason, the rejection should be withdrawn.

Applicants also traverse the double patenting rejection made in view of U.S. Patent No. 5,728,721. Claims 1-7 of the '721 patent do not suggest the claims of the present application because claims 1-7 of the '721 patent are directed to treating hyperacute rejection reactions, rather than acute or chronic rejection reactions. Moreover, claims 1-7 do not specifically suggest treating rejection reactions involving a xenograft transplant. Claims 8-13 of the '721 patent do not specifically suggest the treatment of acute or chronic rejection reactions. The Examiner's comment that claims 8-13 "encompass" the claimed methods is not in itself sufficient to establish a *prima facie* case of unpatentability, absent a teaching or suggestion of the claimed methods.

For all the reasons discussed above, applicants respectfully request that the Examiner withdraw the double patenting rejections.

U.S. Patent No. 5,688,824 to Williams

During prosecution of parent application no. 09/189,866, the Examiner requested that applicants state which entity between Robert Bartlett (for the present invention) and James Williams (for the invention claimed in U.S. Patent No. 5,688,824) was the prior inventor. *See* Office Action dated January 29, 2003. The requirement was made because the Examiner believed that the claims between the two cases at the time were directed to the same invention and the two cases were commonly assigned. *Id.*

The present application and the '824 patent are no longer commonly owned. The present application is currently assigned to Sanofi-Aventis Deutschland GmbH, as

recorded on November 22, 2005 at Reel 016800, Frame 0538. The '824 patent has recently been assigned back to James Williams, as recorded on December 12, 2006 at Reel 018616, Frame 0107. In view of the fact that the two cases are not commonly owned, the requirement that applicants state which entity was the prior inventor should no longer apply.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: December 15, 2006

By: 

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